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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,669	10/16/2003	Wayne L. Ryan	12642.0065.NPUS01	2668

23369 7590 04/17/2009

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/605,669	RYAN, WAYNE L.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/20/09 (2), 3/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-27 as presented in the 2/18/09 reply are currently pending.

Election/Restrictions

As noted in the Office communication mailed 2/12/09, Groups II and III have been rejoined to Group I.

Applicant's election of the species "diazolidinyl urea," "EDTA," "whole blood," and "a packaging means for transporting said collection device" in the reply filed on 3/29/06 is acknowledged. Applicant's further election of the species "a flow cytometer" and "HIV" in the reply filed on 2/18/09 is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Examination on the merits will commence at this time on claims 1-27, to the extent they read on the elected species where applicable.

Specification

The disclosure is objected to because of the following informalities: It recites various trademarks, including "VACUTAINER PLUS" and "HEMOGARD" at page 11; "TROLOX" at page 17; and "KATHON" and "OMADINE" at page 21, without providing generic terminology for these products. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate correction is required for all trade names referenced in the specification.

Claim Objections

Claim 5 is objected to because of the following informalities: The word "polyacrylic" is misspelled at line 2. Furthermore, there is extraneous italicizing at line 2 of claim 16. The word "the" has been inadvertently omitted from claims 3, 4, 6, and 16-19, i.e. "the ratio," "the compounds," and "the concentration." The word "includes" in claim 18 should read "include." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for products and methods that preserve the morphology and antigenic properties of mammalian cells, does not reasonably provide enablement for identifying a sufficient amount of diazolidinyl urea (DU) that preserves the morphology and antigenic properties of each and every type of cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in

the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

In view of the species election, the claims are interpreted as being broadly drawn to a partially evacuated collection device for cells (i.e., any type of cell from any tissue and any organism) comprising DU in a sufficient amount to preserve the "original morphology and antigenic sites" of cells placed therein. Some claims are drawn to methods for making and using such a device. In some dependent claims, the anticoagulant is EDTA. In some dependent claims, the cells to be preserved are those in whole blood. In some dependent claims, the components in the device are sterilized and/or freeze-dried. Some claims list downstream applications for the device.

The claims place no limit on the type of cell to be preserved in the device; the cell may be a mammal, plant, or microbial cell. Ryan (1998, U.S. Patent 5,849,517; reference A3 on 2/20/09 IDS) explicitly teaches that the fixatives recited in the independent claims are disinfectants (column 17, lines 65-66) and therefore kill microbes. Therefore, the skilled artisan would not have a reasonable expectation that there is any amount of DU (or any of the fixatives in claim 1) that could be used to preserve microbes in the manner required by the claims. Paragraph 27 of the instant specification concurs with the Ryan patent on this point.

Applicants present no working embodiment in the specification; the scope of the disclosure appears to be limited to a device and method for preserving mammalian cells

while remaining silent on any other kind of cell (paragraphs 7, 14, 21, 22, 29, and 31). While a singular, narrow working embodiment cannot be a sole factor in determining enablement, its limited showing, in light of the unpredictable nature of the art and the lack of direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of making a collection device for cells; claim 14 is drawn to the collection device itself. It is not clear whether these claims include cells as a necessary component or not. The preamble limitation "collecting device for cells" appears to be a statement of intended use rather than a limitation on the structure of the composition. See M.P.E.P. § 2111.02. Similarly, step (b) of claim 1 and element (b) of claim 14 refer to "said cells," but it is not clear that cells are necessarily a part of the product recited in the claims. Clarification is required.

Independent claims 1, 14, and 27 all require at element (b) that a fixative agent be present in the composition "in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilution of said cells," which raises several issues. First, there is no point of comparison for the relative term "original." It is

not clear which changes are allowed while still preserving this “original” state and which are not. Furthermore, since the composition does not require that cells be present, it is not clear how this requirement necessarily relates to the composition. Third, the scope of “significant dilution” is queried; it is not clear which degrees of dilution are embodied by this limitation and which are not. Clarification of these points is required.

The most critical issue with the limitations at element (b) is the scope of the term “a sufficient amount" to yield the particular outcomes. It is submitted that the analysis prescribed by the M.P.E.P. regarding the phrase “an effective amount" also applies here, i.e. whether the person of ordinary skill in the art could determine from the written disclosure what a sufficient amount is. The specification includes no working examples in which any amount of any fixative agent is combined with any cell such that morphology and antigenic sites are preserved; given that the specification explicitly indicates that the mechanism of action of the claimed fixative agents is unknown (paragraphs 27 and 28), it is not clear that the skilled artisan could identify the "sufficient amount" of even the elected fixative agent that preserves all morphological and antigenic properties of each and every type of cell (since the claims do not place any constraint on the cells). Clarification is required.

Because claims 2-13 and 15-26 depend from indefinite claims 1 and 14 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claims 3, 4, 16, and 17 recite concentrations (“g/mL”), but there is no basis provided in the claims for these comparative limitations. Clarification is required.

Claims 6 and 19 refer to a ratio between the anticoagulant and the fixative agent in the collection device, but it is not clear whether this ratio is a weight ratio, molar ratio, or some other type. Clarification is required.

Claim 9 recites surface areas that "can come into physical contact with said collected and preserved cells," which is confusing for two reasons. First, the limitation "said collected and preserved cells" has no antecedent basis in claim 1, which does not recite these terms and, as discussed above, does not rigorously require the composition to contain cells. Second, the phrase "can come into contact" is queried. The conditions for contact are not pointed out, and since claim 1 is drawn to a method for making a collection device that does not necessarily contain cells, it is not clear whether contact is required. Clarification is required.

It is noted that while they are not elected species, claims 12 and 25 recite numerous trade names referring to products. M.P.E.P. § 2173.05(u) recites, "It is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name." If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). These claims have not been considered on their merits beyond the elected species recited therein, "a flow cytometer," but applicant is encouraged to address this situation prior to the time of allowance.

Claim 14 requires a container having “an open end and a closed end" with “a closure at said open end of said container,” which is confusing. It is not clear how an end of a tube can be both open and have a closure. Clarification is required.

Claim 22 recites surface areas “that can come into physical contact with said cells,” which is confusing. The conditions for contact are not pointed out, and since claim 1 is drawn to a method for making a collection device that does not necessarily contain cells, it is not clear whether contact is required. Clarification is required. Clarification is required.

Claims 25 and 26 set forth uses for the composition in claim 14 without reciting any positive method steps. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Clarification is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25 and 26 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-17, and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan (1998, U.S. Patent 5,849,517; reference A3 on 2/20/09 IDS) taken in view of Camiener (1999, U.S. Patent 5,977,153; reference A4 on 2/20/09 IDS) and Glover et al. (1975, U.S. Patent 3,879,295; reference A) and Louderback (1976, U.S. Patent 3,973,913; reference B). In the interest of compact prosecution, the claims are interpreted as being drawn to a collection device comprising an anticoagulant and diazolidinyl urea (DU, a fixative), wherein the device has at least a partial vacuum inside. Some claims are drawn to methods for making and using such a device. In some dependent claims, the anticoagulant is EDTA. In some dependent claims, the cells to be preserved are those in whole blood. In some dependent claims, the components in the device are sterilized and/or freeze-dried. Some claims list downstream applications for the device.

Ryan teaches collecting whole blood samples in a vacutainer containing EDTA and adding a fixative solution containing DU, then processing the sample using flow cytometry (Specific Examples I and II at columns 8-9). Ryan teaches that the amount of DU to include in the collection device is that effective to fix or stabilize cells and tissues while preserving antigenic sites thereof (column 7, lines 39-45; see also column 6, lines

56-60, and column 3, lines 30-39). Ryan teaches that the amount of DU may vary (column 4, lines 49-51; column 17, line 66, through column 18, line 1; and claims 4, 8, and 19). Ryan teaches that whole blood preserved in their device may be screened for HIV (Specific Examples XIII and XIV at columns 16-18). Ryan teaches that DU is a disinfectant (column 17, lines 65-66), so it necessarily sterilizes the device. Ryan teaches shipping samples preserved using the device to distant sites, implying use of a packaging means for such transporting (column 3, lines 45-46).

Ryan does not teach an embodiment in which DU and an anticoagulant (EDTA, for example) are contained within a collection device with an internal pressure lower than atmospheric pressure. Ryan does not teach an embodiment in which the active agents are freeze-dried.

Camiener teaches that DU may be evaporated to a solid, dry mass that maintains its fixative ability (Examples 1 and 3 at columns 8 and 9). Camiener suggests a composition comprising DU and EDTA (column 8, lines 13-15). Camiener teaches that lyophilization (freeze-drying) may also be used to dry the fixative (column 9, lines 31-32). The dried fixative of Camiener is suitable for preserving biological materials, including blood (claim 1 and column 7, lines 42-47).

Glover teaches a tissue collection device that holds a vacuum inside and may be sealed with a stopper (Abstract). The title of Glover refers to the device as a vacutainer. The device of Glover contains a vacuum sufficient to allow cells to be collected (column 6, lines 36-41). Glover teaches adding a clotting agent after the sample is collected (column 6, lines 53-55).

Louderback teaches that EDTA is an anticoagulant (column 3, lines 30-32).

A person of ordinary skill in the art would have had a reasonable expectation of success in including the dried DU of Camiener within the EDTA-containing evacuated device of Ryan for the purpose of preserving cells because Camiener teaches that drying DU does not affect its preservative properties. The skilled artisan would have had a further expectation of success in employing the evacuated tissue collection device of Glover as the "vacutainer" of Ryan because Glover's device can be used to collect blood. The person of ordinary skill in the art would have had a further reasonable expectation in combining the teachings of Ryan and Glover because Louderback teaches that the EDTA in the container of Ryan prevents clotting, and because Glover's teaching that clotting agents should be added once blood has been collected clearly indicates that clotting prior to processing is undesirable.

The skilled artisan would have been motivated to substitute the dried DU of Camiener for the DU solution taught by Ryan because Camiener teaches that DU maintains its fixative ability after being dried and is useful for fixing and preserving cells, which is the same utility sought by Ryan.

The selection of the amount of DU and EDTA to include in the collection device would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Ryan teaches that these amounts may be modified as necessary. A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include DU and EDTA within an evacuated container in

amounts sufficient to preserve the morphology and antigenic sites of cells stored in said container because Ryan teaches that DU has such preservative activity and because Glover teaches such a partially evacuated device for collecting cells. It would have been further obvious to the skilled artisan in the art at the time the invention was made to dry DU and/or EDTA within the collection device because Camiener teaches that such dried compositions are useful for fixing and preserving collected cells.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan, Camiener, Glover, and Louderback as applied to claims 1-4, 6-17, and 19-27 above, and further in view of Deich et al. (1992, U.S. Patent 5,110,908; reference C).

The teachings of Ryan, Camiener, Glover, and Louderback are relied upon as above. Furthermore, Ryan teaches that samples collected in the device may be used in the preparation of vaccines (column 3, lines 35-39).

Ryan, Camiener, Glover, and Louderback do not teach including a polyacrylic acid in the collection device.

Deich teaches that polyacrylic acid is an adjuvant suitable for use in vaccine production (column 21, line 44, through column 22, line 6).

A person of ordinary skill in the art would have had a reasonable expectation of success in including the polyacrylic acid of Deich in the collection device of Ryan taken in view of Camiener, Glover, and Louderback because Deich teaches that polyacrylic

acid may be contacted with vaccines. The skilled artisan would have been motivated to include polyacrylic acid in the collection device to facilitate the production of vaccines, as taught by Ryan.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include the polyacrylic acid of Deich in the collection device of Ryan taken in view of Camiener, Glover, and Louderback because both are taught as being useful in vaccine production.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 27 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 12, and 13 of U.S. Patent No. 5,849,517 in view of Glover et al. (1975, U.S. Patent 3,879,295).

Claim 27 is interpreted as being drawn to a method for preparing cells for analysis comprising providing an at least partially evacuated device comprising an anticoagulant agent and DU and collecting cells in said device. Claim 1 of the '517 patent is drawn to a method of preserving tissue samples by suspending them in a solution comprises DU in one embodiment; claims 7 and 8 of the '517 patent allow that the solution further comprise EDTA. Instant claim 27 does not limit the type of cell being analyzed; claims 13 and 14 of the '517 patent list particular species of cells.

The claims of the '517 patent are silent as to the method being carried out in an at least partially evacuated container.

Glover teaches a tissue collection device that holds a vacuum inside and may be sealed with a stopper (Abstract). The device of Glover contains a vacuum sufficient to allow cells to be collected (column 6, lines 36-41).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to carry out the preservation method of the '517 claims in the device of Glover because Glover's device is explicitly taught as being useful for tissue and cell collection. A blood sample collected into the device of Glover comprising the DU and EDTA of the '517 claims would inherently form a solution in which the sample becomes suspended.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651